Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL J. POWELL, RICHARD C. TITMAS and RICHARD J. MASSEY

Appeal No. 2003-0743
Application No. 09/303,716

ON BRIEF

Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 36, 39, 42, 45 and 48; claims 26-34, 37, 40, 43, 46 and 49, also pending in the application, have been withdrawn from consideration; claims 1-25, 35, 38, 41, 44, 47 and 50-55 have been canceled. The claims on appeal are reproduced in the Appendix accompanying appellants' Brief.

The issue appellant would have us consider is whether the specification provides an adequate written description of the subject matter of claims 36, 39, 42, 45 and 48. For the reasons which follow, we reverse the examiner's rejection.

BACKGROUND

According to the specification, "antibodies and enzymes share a fundamental similarity in that both are specialized proteins that bind to other molecules" (page 3). "Antibodies bind molecules in their ground state while enzymes bind molecules in higher energy states." Normally, "[t]he binding of [ ] antibody to the [molecule] enables the [molecule] to be removed from the organism[,]" while "[e]nzymes are biological catalysts which bind a molecule in such a way that the activation energy of a reaction involving a molecule or substrate is lowered, thereby increasing the rate of the reaction" (id.). "[I]t has been discovered[, however,] that antibodies can be elicited to catalyze a variety of chemical reactions" (id., page 2).

"During the course of [a] chemical reaction, the reactants undergo one or more transitions through intermediate structures or transition states which are energetically less favorable than either the reactant or the product. The hydrolysis reaction of a peptide linkage or an ester bond in an aqueous medium passes through a tetrahedral carbon transition state . . . [wherein] a tetrahedral carbon atom is bonded to: a carbon atom of the acid portion of the peptide linkage or ester bond; two oxygen atoms, one corresponding to the carbonyl group and the other corresponding to a hydroxyl ion or water molecule of the medium; and either the oxygen atom of the alcohol portion of an ester or the nitrogen atom of the amine portion of the peptide linkage" (Specification, pages 3-4).

"The energy required to achieve a transition state is denoted as the activation energy, which may also be considered as the difference in energy between the energy of the transition state and the energy of the reactants" (Specification, pages 32-33).

"Catalysts increase chemical reaction rates by lowering the activation energy of a reaction. Antibodies elicited to a hapten . . . [which] resemble[s] the presumed transition state structure (i.e., a transition state analog), can catalyze reactions . . . [by] stabiliz[ing] the energy of the transition state relative to reactants and products[,] . . . [an] approach [that] has been successfully demonstrated in the generation of several catalytic monoclonal antibodies" (id, page 33).

DISCUSSION

Claims 36 and 39 are directed to catalytic antibodies elicited by an antigen comprising the boron-containing hapten of formula I; claim 42 is directed to a method for producing catalytic antibodies specific for the boron-containing hapten of formula I; and claims 45 and 48 are directed to catalyzing the cleavage or formation of a peptide linkage or an ester bond in a molecule using catalytic antibodies elicited by an antigen comprising the boron-containing hapten of formula I.[1]

According to the examiner, the hapten of formula I "has a very wide range of possibilities" but the specification "does not teach that any of the myriad possibilities . . . will make antibodies that have catalytic activity," much less "which molecules are substrates for cleavage or formation of an ester or peptide bond" (Answer, page 3), thus, the subject matter of the claims "was not described in the specification in such a way as to reasonably convey . . . that [appellants], at the time the application was filed, had possession of the claimed invention" (Answer, page 3).

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[1] The boron-containing hapten depicted in the claims on appeal was originally designated "formula II." The designation of the hapten in the claims was changed to "formula I" by the preliminary amendment filed April 30, 1999 (paper no. 3), but the designation of the boron-containing hapten throughout the specification is still "formula II."

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" Enzo Biochem v. Gen-Probe, Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) (citation omitted). In Enzo, the court explained that one way a claim may satisfy the written description requirement is by coupling a "functional characteristic . . . with a disclosed correlation between that function and a structure that is sufficiently known or disclosed" (id.).

More to the point, in Enzo, the court adopted the PTO's internal guidelines for determining compliance with the written description requirement (Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description Requirement," 66 Fed. Reg. 1099 (January 5, 2001), also available at http://www.uspto.gov/web/patents/guides.htm), at least to the extent that "the PTO would find compliance with § 112, ¶ 1, for a claim to an 'isolated antibody capable of binding to antigen X,' notwithstanding the functional definition of the antibody, in light of 'the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that antibody technology is well developed and mature.'" Enzo, 296 F.3d at 1324-25, 63 USPQ2d at 1613 (Fed. Cir. 2002).[2]

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[2] The example referred to here stipulates that antigen X has been isolated and characterized and that the specification includes a complete protocol for its isolation. "Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that antibody technology is well developed and mature," the guidelines indicate that the written description requirement is met because "one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X" ("Application of Guidelines," Example 16).

Here, as explained in the specification, the antibodies required by each of the claims on appeal are elicited by boron-containing haptens which "assume a tetrahedral like configuration upon reaction with water in an aqueous environment" (page 41), "mimic[king] the transition state in the cleavage or formation of a peptide linkage or an ester bond in a molecule" (pages 16-17). Moreover, "amino acid side-chain sub-sites on either side of the tetrahedral transition state analog . . . provide for the elicitation of catalytic antibodies capable of recognizing a specific amino acid sequence" and "catalyzing the selective cleavage or formation of a predetermined peptide linkage or an ester bond in a native polypeptide sequence" (id, page 18).

Thus, the specification teaches that a function of the claimed antibodies (the ability to catalyze a reaction, particularly the ability to catalyze the cleavage or formation of a peptide linkage or an ester bond) is coupled to a particular structure (the boron-containing transition state analog of formula I). The specification also teaches that the binding specificity of the catalytic antibodies (an additional function) is conferred by the structure of the amino acid side-chains carried by the tetrahedral transition state analog.

Having reviewed the claims and specification in light of the standard discussed in Enzo, we find that the claims are supported by an adequate written description. The rejection of the claims under the first paragraph of 35 U.S.C. § 112 is reversed.

REVERSED

Toni R. Scheiner
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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